DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0498]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Medical Devices; Device Tracking

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices; Device Tracking—21 CFR Part 821 (OMB Control Number 0910–0442)—Extension

Section 211 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) became effective on February 19, 1998. It amended the previous medical device tracking provisions in section 519(e)(1) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(e)(1) and (e)(2) that were added by the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629). Unlike the tracking provisions under SMDA, which required tracking for any device meeting certain criteria, FDAMA allows FDA discretion in applying tracking requirements to devices that meet certain criteria and provides that tracking requirements can be imposed only after FDA issues an order. In the **Federal Register** of February 8, 2002 (67 FR 5943), FDA issued a final rule to conform existing tracking regulations to changes in tracking provisions effected by FDAMA (part 821 (21 CFR part 821)).

Current section 519(e)(1) of the act, as amended by FDAMA, provides that FDA may by order require a manufacturer to adopt a method of tracking a class II or class III device, if the device meets one of three criteria: (1) The failure of the device would be reasonably likely to have serious adverse health consequences; (2) the device is intended to be implanted in the human body for more than 1 year (referred to as a ''tracked implant''); or (3) the device is life-sustaining or life-supporting (referred to as a ''tracked l/s-l/s device'') and is used outside a device user facility.

Tracking information is collected to facilitate identifying the current location of tracked devices and patients possessing the devices, to the extent that patients permit the collection of identifying information. Manufacturers and, as necessary, FDA use the data to expedite the recall of distributed devices that are dangerous or defective, and to facilitate the timely notification of patients or licensed practitioners of the risks associated with the devices.

Respondents to this collection of information are manufacturers, importers, and distributors of tracked implants or tracked l/s-l/s devices used outside a device user facility. Distributors include multiple and final distributors, including hospitals.

The regulations include requirements for exemptions and variances; system and content requirements of tracking; obligations of persons other than device manufacturers, e.g., distributors; records and inspection requirements; confidentiality; and record retention requirements.

In the **Federal Register** of November 30, 2004 (69 FR 69604), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
821.2 (also 821.30(e))	4	1	4	12	48
821.25(a)	1	1	1	76	76
821.25(d)	22	1	22	2	44
821.30(a) and (b)	17,000	72	1,222,725	0.1666	203,706
821.30(c)(2)	1	1	1	28	28
821.30(d)	17,000	15	259,186	0.1666	43,180
Total					247,082

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
821.25(b)	229	46,260	10,593,433	0.2899	3,071,036
821.25(c)	229	1	229	63.0	14,430
821.25(c)(3)	229	1,124	257,454	0.2899	74,636
Total					3,160,102

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The annual reporting burden hours to respondents for medical device tracking is estimated to be 247,082 hours, and recordkeeping burdens for respondents is estimated to be 3,160,102 hours. These numbers have been rounded up. The estimates cited in tables 1 and 2 of this document are based primarily upon the data and methods provided in FDA's 1999 assessment entitled ''A Cost Assessment of Medical Device Tracking.'' Using implantation procedures from the National Center for Health Statistics, FDA applied a 2 percent annual growth rate to estimate the number of procedures for tracked implant devices from 1997–2006. The assessment also used unit shipment data in combination with various growth rates to estimate annual/sales distribution for the tracked l/s-l/s devices over the same time period. Additionally, the assessment estimates the industry burden for developing and maintaining tracking systems for these devices from 1997–2006.

For the annual recordkeeping burden, the number of manufacturers subject to device tracking (229) is based on data from FDA's manufacturers database. FDA issued tracking orders to 20 additional manufacturers during the time period 2002–2004. Under § 821.25(c), the additional manufacturers collectively bear a one-time burden of 10,560 hours to develop a device tracking system. FDA's estimate of 17,000 distributor respondents contained in the assessment is derived from Dun & Bradstreet sources on medical equipment wholesalers,

retailers, home care dealers, and rental companies. Health Forum, an American Hospital Association Co., provided statistics on hospitals.

Dated: February 25, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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